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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,617	DENG, WENLONG	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-18* is/are pending in the application.

4a) Of the above claim(s) *17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on January 11, 2005 with the cancellation of Claims 1-10, and newly added Claims 11-18.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 11-18 are currently pending.

Newly submitted claims 17 and 18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims 17 and 18 are drawn to "A method for treating the rheumatoid and rheumatoid arthritis, comprising: administering the pharmaceutical mixture of claim 11 to a patient in need thereof" and "The method according to claim 17, wherein the pharmaceutical mixture is administered in the form of a hard capsule, soft capsule, tablet, granule, or injection". No claims were previously examined that related to a method of treating rheumatoid and rheumatoid arthritis.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 17 and 18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 11-16 are under examination.

Claim Objections

Claim 14 is objected to because of the following informalities: "specific density" in line 23 should either be written as specific gravity or relative density. Appropriate correction is required. Newly applied as necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide prior support or antecedent basis for the language "A method for preparing the pharmaceutical mixture according to claim 11, comprising: providing and cutting the Tripterygium hypoglaucum (Levl.) Hutch into pieces; providing and cutting the Epimedium brevicornum Maxim into pieces; providing and optionally crushing the Lycium barbarum L; providing and optionally crushing the Cuscuta chinensis Lam; optionally combining two or more of the herbs to make an herb mixture; extracting the herb mixture or individual herbs in a 0 to 95% alcohol/water mixture, at a temperature in the range of 1 to 98 °C, 1 to 4 times, to form one or more extracted liquor(s)/alcohol mixtures; optionally mixing the extracted liquor(s)/alcohol mixtures; recovering the extracted liquors from the extracted liquor(s)/alcohol mixtures; condensing, drying, and smashing the extracted liquor(s) to form extracted herb powders; and, mixing the

extracted herb powders uniformly or proportionally to form a pharmaceutical mixture", as claim 13, and "A method for preparing the pharmaceutical mixture according to claim 11, comprising: providing and cutting *Tripterygium hypoglaucum* (Levl.) Hutch into small pieces; extracting from the *Tripterygium hypoglaucum* (Levl.) Hutch three times with water a decoction fluid, wherein the weight of the water is 13, 10, 10 times the weight of the un-extracted herb respectively, with each extraction lasting 1 hour; providing and cutting *Epimedium brevicornum* Maxim into segments; extracting from the *Epimedium brevicornum* Maxim three times with water a decoction fluid, wherein the weight of the water is 15, 10, 10 times the weight of the un-extracted herb respectively with each extraction lasting 1 hour; crushing *Lycium barbarum* L to a coarse powder and immersing the powder in 20 times by weight of water, at 80°C-95°C for 1 hour; crushing *Cuscuta chinensis* Lam to a coarse powder and immersing the powder in 31 times by weight of water, at 90°C for 1 hour; filtering the decoction fluid or immersion fluid of four herbs separately; pouring each filtered fluid through a macroporous polymeric adsorbent resin column; eluting each column with 70% ethanol until the color of effluent becomes deep; continuously collecting the effluent until the color of the effluent becomes very weak; recovering the alcohol in the effluent of each herb; concentrating and drying the remaining fluid of each herb to form an extract powder from each herb; and, mixing the extract powder from each herb uniformly and proportionally to form a pharmaceutical mixture" and failing to comply with the written description requirement. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed 9 January 2007 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the instant case, the original Claim 5 (which appears to be a combination of newly submitted Claim 13 and newly submitted Claim 14) did not disclose the method steps that Applicant is claiming, wherein Applicant claimed, as Claim 5, "A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it includes the processes under-mentioned: The raw herbs are weighed, and Epimedium brevicornum Maxim.and Tripterygium hypoglaucum (Levl.) Hutch.were cut into pieces respectively; including raw material or crushed powder of Lycium barbarum L. and Cuscuta chinensis Lam., four herbs hereinbefore, were extracted with 0-95% ethanol at 10-98°C respectively or combinatively for continuing 1-4 times. Ethanol was recycled respectively or combinatively in extracted fluid, then extraction was concentrated, dried, crushed, mixed uniformly or proportionally, manufactured to dosage form adopted in clinical work; Raw herbs were weighed: Epimedium brevicornum Maxim.and Tripterygium hypoglaucum (Levl.) Hutch.were cut into pieces, boiled out in water for three times respectively, and Lycium barbarum L. or Cuscuta chinensis Lam.were immersed in water of 80°C - 95 °C for 1-3 times respectively. Decoction or immersion fluids of three times of each herb were blended respectively, then mixture fluid was respectively poured through corresponding macropore polymeric adsorbent column. After absorption, resin column was washed with water until effluent became clear, then was eluted with 30-99.5%

ethanol until color of effluent became deep. Then eluent was collected until color of eluent became from deep to very weak while ethanol liquid was forced out from the column with water. Eluent was mixed with the ethanol liquid. The weight of total eluent was 1-8 fold of the herbs; eluent of each herbs was recycled, concentrated to specific gavity of 1.10 respectively, then extractive of every herbs were obtained by respective or combinative spray drying, which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work", and "A method of preparing the pharmaceutical composition according to claim 1, 2 or 3, characterized in that, it includes the processes under-mentioned: Tripterygium hypoglaucum (Levl.) Hutch. were cut into pieces, extracted three times after 13, 10, 10-fold added in respectively, each time lasting 1 hour; Epimedium brevicornum Maxim. was cut into segments, extracted three times after 15, 10, 10-fold water was added in respectively, each extraction lasting 1 hour; Lycium barbarum L. was crushed to raw material, and immersed in 20-fold water of 80°C-95 °C for 1 hour; Cuscuta chinensis Lam. was crushed to raw powder, immersed in 31-fold water of 90°C for 1 hour; decoction fluid or immersion fluid of four herbs were filtrated respectively, poured through WLD or D 101 or other type of macropore polymeric adsorbent column, eluted with 70% ethanol, when the color of effluent became deep significantly, eluent was commenced to collect; when the color of effluent became very weak, elution was over. Eluent of each herbs was recycled to get ethanol, concentrated, dried, finally extractive drug powder was obtained; which were mixed uniformly and proportionally, manufactured to dosage form adopted in clinical work" as Claim 7 (which appears to be newly submitted claim 16).

In amended Claim 13, Applicant claims, "A method for preparing the pharmaceutical mixture according to claim 11, comprising: providing and cutting the Tripterygium hypoglaucum (Levl.) Hutch into pieces; providing and cutting the Epimedium brevicornum Maxim into pieces; providing and optionally crushing the Lycium barbarum L; providing and optionally crushing the Cuscuta chinensis Lam; optionally combining two or more of the herbs to make an herb mixture; extracting the herb mixture or individual herbs in a 0 to 95% alcohol/water mixture, at a temperature in the range of 1 to 98 °C, 1 to 4 times, to form one or more extracted liquor(s)/alcohol mixtures; optionally mixing the extracted liquor(s)/alcohol mixtures; recovering the extracted liquors from the extracted liquor(s)/alcohol mixtures; condensing, drying, and smashing the extracted liquor(s) to form extracted herb powders; and, mixing the extracted herb powders uniformly or proportionally to form a pharmaceutical mixture", which introduces the following new limitations, "providing" (in lines 3- 6), "optionally crushing the Lycium barbarum; providing and optionally crushing the Cuscuta chinensis" (in lines 5 and 6), "optionally combining two or more of the herbs to make an herb mixture" (in line 7), "extracting the herb mixture of individual herbs in a 0 to 95% alcohol/water mixture, at a temperature in the range of 1 to 98 °C, 1 to 4 times, to form one or more extracted liquor(s)/alcohol mixtures; optionally mixing the extracted liquor(s)/alcohol mixtures; recovering the extracted liquors from the extracted liquor(s)/alcohol mixtures; condensing, drying and smashing the extracted liquor(s) to form extracted herb powders; and, mixing the extracted herb powders uniformly or proportionally to form a pharmaceutical mixture", and "A method for preparing the

pharmaceutical mixture according to claim 11, comprising: providing and cutting *Tripterygium hypoglaucum* (Levl.) Hutch into small pieces; extracting from the *Tripterygium hypoglaucum* (Levl.) Hutch three times with water a decoction fluid, wherein the weight of the water is 13, 10, 10 times the weight of the un-extracted herb respectively, with each extraction lasting 1 hour; providing and cutting *Epimedium brevicornum* Maxim into segments; extracting from the *Epimedium brevicornum* Maxim three times with water a decoction fluid, wherein the weight of the water is 15, 10, 10 times the weight of the un-extracted herb respectively with each extraction lasting 1 hour; crushing *Lycium barbarum* L to a coarse powder and immersing the powder in 20 times by weight of water, at 80°C-95°C for 1 hour; crushing *Cuscuta chinensis* Lam to a coarse powder and immersing the powder in 31 times by weight of water, at 90°C for 1 hour; filtering the decoction fluid or immersion fluid of four herbs separately; pouring each filtered fluid through a macroporous polymeric adsorbent resin column; eluting each column with 70% ethanol until the color of effluent becomes deep; continuously collecting the effluent until the color of the effluent becomes very weak; recovering the alcohol in the effluent of each herb; concentrating and drying the remaining fluid of each herb to form an extract powder from each herb; and, mixing the extract powder from each herb uniformly and proportionally to form a pharmaceutical mixture", as claim 16, thereby introducing the new limitations, "small pieces" in line 3, "with water a decoction fluid: in line 5, "a coarse powder" in lines 11 and 13, and "mixing the extract powder from each herb uniformly and proportionally to form a pharmaceutical mixture" in lines 22 and 23, which is considered to be new matter. Insertion of the above mentioned

claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of these concepts. There are methods of making composition comprising Tripterygium hypoglaucum, Epimedium brevicornum, Lycium barbarum and Cuscuta chinensis provided on pages 6-9, however these methods do not contain the newly inserted limitations described above. This is not sufficient support for the limitations. This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 13 recites the limitation "the herbs" in line 7. There is insufficient antecedent basis for this limitation in the claim.

The metes and bounds of Claim 16 are rendered uncertain by the phrase "wherein the weight of the water is 13, 10, 10 times the weight of the unextracted herb, respectively" because it is unclear as to what Applicant means. First of all, is Applicant trying to describe the amount of water in each extract? If so, is Applicant saying that the first extraction is carried out with water, wherein the amount of water is 13 times greater than the amount of each component or in relation to the whole composition or is Applicant saying that each extraction is carried out with water in an amount of 13 times the amount of either each component or the whole composition (it is unclear which), 10 times the amount of either each component or the whole composition and 10 times the amount of either each component or the whole composition? Furthermore, the amounts of the ingredients are not set forth in terms of either 'by weight" or "by volume" amount of the total composition and do not indicate what the amount of the water is in relation to. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 16 recites the limitation "the unextracted herb" in lines 5 and 6. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Claim Rejections - 35 USC § 102

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 9 January 2007, with respect to the rejection(s) of claim(s) 1-3 under Xu et al. (U*, CN 1178697 A, Abstract only. Please note that in Applicant's response, the name is referred to as Xu, however, it appears that the Inventors' names are Ruixin Xu and Ming Xu, so in this Office Action, the reference is herein referred to as Xu have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 9 January 2007, with respect to the rejection(s) of claim(s) 1-3 under Xu et al. (U*, CN 1178697 A, Abstract only. Please note that in Applicant's response, the name is referred to as Guo, however, it appears that the Inventors' names are Ruixin Xu and Ming Xu, so in this Office Action, the reference is herein referred to as Xu) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made 35 U.S.C. 103(a) as being unpatentable over Xu et al. (U*, CN 1178697 A, Abstract only. Please note that in Applicant's response, the name is referred to as Guo, however, it appears that the Inventors' names are Ruixin Xu and Ming Xu, so in this Office Action, the reference is herein referred to as Xu), in view of Li et al. (V, CN 1051859 A, Abstract only), Xiong et al. (W, CN 1097313 A, Abstract only), Wang (X, CN

1146348 A, Abstract only), Green (U1, "The Herbal Medicine-Maker's Handbook: A Home Manual. 2000, Berkeley, California: The Crossing Press. Pages 109, 112-114, 146, 151, 299, 309 and 310), Hu et al. (V1, Se Pu. 1999; 17(3): 265-267. Abstract only), Li (W1, Hua Xi Yi Ke Da Xue Xue Bao. 1995; 26(1): 66-69. Abstract only), Xie (X1, Se Pu. 1997; 15(1): 54-56. Abstract only) and Zhang (U2, ZhongXu Zhong Yao Za Zhi. 1998; 23(9):549-550. Abstract only).

Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Xu et al. (U*, CN 1178697 A, Abstract only. Please note that in Applicant's response, the name is referred to as Guo, however, it appears that the Inventors' names are Ruixin Xu and Ming Xu, so in this Office Action, the reference is herein referred to as Xu), in view of Li et al. (V, CN 1051859 A, Abstract only), Xiong et al. (W, CN 1097313 A, Abstract only), Wang (X, CN 1146348 A, Abstract only), Green (U1, "The Herbal Medicine-Maker's Handbook: A Home Manual. 2000, Berkeley, California: The Crossing Press. Pages 109, 112-114, 146, 151, 299, 309 and 310), Hu et al. (V1, Se Pu. 1999; 17(3): 265-267. Abstract only), Li (W1, Hua Xi Yi Ke Da Xue Xue Bao. 1995; 26(1): 66-69. Abstract only), Xie (X1, Se Pu. 1997; 15(1): 54-56. Abstract only) and Zhang (U2, ZhongXu Zhong Yao Za Zhi. 1998; 23(9):549-550. Abstract only).

Xu teaches a medicine for rheumatism comprising Tripterygium hypoglaucum and the fruit of barbary wolfberry (which is synonymous with *Lycium barbarum*).

Li teaches a therapeutic composition for treating rheumatoid arthritis obtained by extraction of *Tripterygium wilfordii* (which is synonymous with *Tripterygium hypoglaucum*), adding ethanol and combining with aqueous beta-cyclodextril solution.

Xiong teaches a snake spirit for treating rheumatism comprising herb of shorthorned epimedium (which is synonymous with *Epimedium brevicornum*) and ripe fruit of barbary wolfberry (*Lycium barbarum*).

Wang teaches a multi-functional health care medicinal liquor comprising fruit of Chinese wolfberry (which is synonymous with *Lycium barbarum*) and seed of Chinese dodder (which is synonymous with *Cuscuta chinensis*) having a curative effect for rheumatism.

Green teaches a method of preparing a decoction, which are liquid preparations made by boiling either fresh or dehydrated herbal substances with water or other fluids. Green further teaches that herbs to be decocted should be cut or ground depending upon the degree of fineness depending upon the nature of the tissue. Green further teaches that when fresh, undried herbs are used in a decoction, the roots should be cut into very thin slices, barks and woods should be shaved down to small pieces, seeds should be lightly crushed and leaves and whole herbs only moderately cut (See pages 112 and 113). Green further teaches 25 grams of herb (about 1 ounce) into a suitable vessel with a cover (use half to three quarters this amount of herb if you want a weaker decoction) and pour 500 ml (approximately 1 pint) of cold water onto it. Green further teaches macerating/soaking the herb for a few hours prior to heating to ensure the complete extraction of all soluble principles from the herb. Green further teaches covering the container well and bringing the ingredients to a boil. Green further teaches decreasing the heat and simmering the mixture for 10 to 15 minutes (the harder the material, the longer the simmering time of extraction). Green further teaches that if not

specified, the extraction time must be determined by observation, common sense and experience. Green further teaches after decoction, press the herb to make sure all of the solution is removed from the marc, allow the pressed decoction to cool to a temperature below 104 °F (40 °C) and strain the liquid. Green further teaches that after it cools, this decoction can be further strained using a filter paper, then, principles, which are soluble only in hot water are mostly precipitated and, if desired, generally can be removed without weakening the medicinal value of the preparation (See page 114). Green further teaches a method of making a cold infusion using 1 part of herb to 20 parts of water of coarsely ground herb to 500 ml of cold water; put the herb in the water and let it remain overnight at room temperature; with cold infusion it is recommended that the herb be contained in a small cotton pouch, suspended in the water overnight and squeezed out when the infusion process is complete; strain and press the marc (See page 109). Green further teaches a method of making herbal tinctures, which are an alcohol or aqueous alcohol solution (See page 146), wherein the steps are as follows: chop and weight the plant and place it in a large jar, prepare custom menstruum, which comprises 80 proof or 100-proof vodka, wherein 80-proof vodka is approximately 40% alcohol by volume and 100-proof vodka is approximately 50% alcohol by volume; cap the jar tightly, shake the tincture frequently for 14 days, then let sit another day; decant the tincture, press the remaining wet pulp and combine the two liquids; filter if desired (See page 151). Green further teaches that filtration is employed when the solid matter to be removed from a liquid solution is not present in a large quantity and it is done by submitting the mixture to the separating action of certain

materials, which allow the fluids to pass through, but which block the passage of the solid particles. Green further teaches that the most common and most easily attainable filtering material used is a paper filter, such as a coffee filter, however cotton, muslin, flannel or woolen cloth may also be used (See page 299). Green further teaches that dried plant material may be subdivided in a process called "powdering". Green further teaches that dried herbs are powdered prior to dispensing and that in pharmacy, the act of powdering is also referred to as comminution or tituration, which means literally to rub, crush, grind, pound and pulverize into fine particles or into a powder. Green further teaches that water softens and easily penetrates powdered herb, causing the powder to expand; however, alcohol has a hardening effect as it thoroughly dehydrates plant material, leaving behind only hardened cellulose and other plant solids. Green further teaches a menstuum containing 60 percent or more absolute alcohol tends to harden plant tissue, so a finer powder is more efficient for those plants requiring a strongly alcoholic menstruum. Green further teaches that powdering should be done only just prior to your actual need for it and once powdered, many of the plants constituents dissipate rapidly with the passage of time and that herbs should be stored in as whole a state as possible in order to inhibit oxidation and loss of volatile oils. Green further teaches that herbal powders can be administered in capsules or orally as it is being placed on the tongue (See pages 309 and 310).

Hu teaches a method of isolating tannins from *Tripterygium wilfordii* (which is synonymous with *Tripterygium hypoglaucum*) by column chromatography using a YWG column and using methanol and buffer as the eluant.

Li teaches a method of analyzing icariin in medicines containing *Epimedium brevicorum*, wherein ODS is used as an analytical column and methanol and buffer is used as an eluent.

Xie teaches a method of extracting and isolating an active component from *Lycium barbarum* comprising passing an extract of *Lycium barbarum* through a cation-exchange column and the effluent is derivatized prior to high performance liquid chromatographic separation on a Zorbax-C8 column, wherein the mobile phase is methanol and buffer.

Ye teaches a method of identifying seeds of *Cusuta chinensis* by running a sample on a Hypersil-ODS column with methanol and a buffer as the eluent.

The teachings Xu, Li, Xiong, Wang, Green, Hu, Li, Xie and Zhang are set forth above and applied as before. Xu does not teach a pharmaceutical mixture for treating rheumatism comprising *Tripterygium hypoglaucum* in an amount of 1-4 parts by weight or in an amount of 2 parts by weight, *Epimedium brevicornum* in an amount of 1-4 parts by weight or in an amount of 2 parts by weight, *Lycium barbarum* in an amount of 1-4 parts by weight or in an amount of 1 part by weight and *Cuscuta chinensis* in an amount of 1-4 parts by weight or in an amount of 1 part by weight nor does Xu teach a method for preparing the pharmaceutical method comprising: providing and cutting the Tripterygium hypoglaucum (Levl.) Hutch into pieces; providing and cutting the Epimedium brevicornum Maxim into pieces; providing and optionally crushing the Lycium barbarum L; providing and optionally crushing the Cuscuta chinensis Lam; optionally combining two or more of the herbs to make an herb mixture; extracting the

herb mixture or individual herbs in a 0 to 95% alcohol/water mixture, at a temperature in the range of 1 to 98 °C, 1 to 4 times, to form one or more extracted liquor(s)/alcohol mixtures; optionally mixing the extracted liquor(s)/alcohol mixtures; recovering the extracted liquors from the extracted liquor(s)/alcohol mixtures; condensing, drying, and smashing the extracted liquor(s) to form extracted herb powders; and, mixing the extracted herb powders uniformly or proportionally to form a pharmaceutical mixture", "A method for preparing the pharmaceutical mixture according to claim 11, comprising: weighing the raw herbs according to the specified parts by weight; cutting Epimedium brevicornum Maxim into pieces; cutting the Tripterygium hypoglaucum (Levl.) Hutch into pieces; decocting the Epimedium brevicornum Maxim pieces with water three times; decocting the Tripterygium hypoglaucum (Levl.) Hutch pieces with water three times; immersing each ofLycium barbarum L or Cuscuta chinensis Lam in water at a temperature in the range of 80°C - 95°C for 1 to 3 times respectively; blending the decocted and immersed herbs to form a mixed fluid, loading the decocted or immersed fluid from each herb on a corresponding macroporous polymeric adsorbent column; absorbing each decocted or immersed fluid onto the corresponding macropore polymeric absorbent column; washing each resin column with water until effluent becomes clear, eluting each resin column with 30-99.5% alcohol to form an eluting liquor; collecting the eluting liquor while the color ranges from a deep color to a very weak color; forcing alcohol out of the column with water; mixing the alcohol with the eluting liquor, wherein the weight of total eluent is 1 to 8 times the weight of the raw herbs; recovering all 4 of the eluting liquors from the alcohol; separately condensing all

4 of the eluting liquors to a specific density of 1.10; spray drying each of the condensed eluting liquors to form extracted herb powders; and, mixing the herb powders to form the pharmaceutical mixture", "the pharmaceutical mixture according to claim 11, wherein the mixture is in the form of a hard capsule, soft capsule, tablet, granule, or injectable liquid" and "A method for preparing the pharmaceutical mixture according to claim 11, comprising: providing and cutting Tripterygium hypoglaucum (Levl.) Hutch into small pieces; extracting from the Tripterygium hypoglaucum (Levl.) Hutch three times with water a decoction fluid, wherein the weight of the water is 13, 10, 10 times the weight of the un-extracted herb respectively, with each extraction lasting 1 hour; providing and cutting Epimedium brevicornum Maxim into segments; extracting from the Epimedium brevicornum Maxim three times with water a decoction fluid, wherein the weight of the water is 13, 10, 10 times the weight of the un-extracted herb respectively with each extraction lasting 1 hour; crushing Lycium barbarum L to a coarse powder and immersing the powder in 20 times by weight of water, at 80°C-95°C for 1 hour; crushing Cuscuta chinensis Lam to a coarse powder and immersing the powder in 31 times by weight of water, at 90°C for 1 hour; filtering the decoction fluid or immersion fluid of four herbs separately; pouring each filtered fluid through a macroporous polymeric adsorbent resin column; eluting each column with 70% ethanol until the color of effluent becomes deep; continuously collecting the effluent until the color of the effluent becomes very weak; recovering the alcohol in the effluent of each herb; concentrating and drying the remaining fluid of each herb to form an extract powder for

each herb; and, mixing the extract powder from each herb uniformly and proportionally to form a pharmaceutical mixture.

However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the ingredients and amounts of ingredients in a composition administered for treating rheumatism because at the time the invention was made, a medicine for rheumatism comprising Tripterygium hypoglaucum and the fruit of barbary wolfberry (which is synonymous with *Lycium barbarum*) was known, as clearly taught by Xu, as was a therapeutic composition for treating rheumatoid arthritis obtained by extraction of *Tripterygium wilfordii* (which is synonymous with *Tripterygium hypoglaucum*), adding ethanol and combining with aqueous beta-cyclodextril solution, as clearly taught by Li, as was a snake spirit for treating rheumatism comprising herb of shorthorned epimedium (which is synonymous with *Epimedium brevicornum*) and ripe fruit of barbary wolfberry (*Lycium barbarum*), as clearly taught by Xiong, as was a multi-functional health care medicinal liquor comprising fruit of Chinese wolfberry (which is synonymous with *Lycium barbarum*) and seed of Chinese dodder (which is synonymous with *Cuscuta chinensis*) having a curative effect for rheumatism, as clearly taught by Wang, as was a method of preparing a decoction, which are liquid preparations made by boiling either fresh or dehydrated herbal substances with water or other fluids, that herbs to be decocted should be cut or ground depending upon the degree of fineness depending upon the nature of the tissue, that when fresh, undried herbs are used in a decoction, the roots should be cut into very thin slices, barks and woods should be

shaved down to small pieces, seeds should be lightly crushed and leaves and whole herbs only moderately cut, 25 grams of herb (about 1 ounce) into a suitable vessel with a cover (use half to three quarters this amount of herb if you want a weaker decoction) and pour 500 ml (approximately 1 pint) of cold water onto it, macerating/soaking the herb for a few hours prior to heating to ensure the complete extraction of all soluble principles from the herb, covering the container well and bringing the ingredients to a boil, decreasing the heat and simmering the mixture for 10 to 15 minutes (the harder the material, the longer the simmering time of extraction), that the extraction time must be determined by observation, common sense and experience, that after decoction, press the herb to make sure all of the solution is removed from the marc, allow the pressed decoction to cool to a temperature below 104 °F (40 °C) and strain the liquid, hat after it cools, this decoction can be further strained using a filter paper, then, principles, which are soluble only in hot water are mostly precipitated and, if desired, generally can be removed without weakening the medicinal value of the preparation, as clearly taught by Green, as was a method of making a cold infusion using 1 part of herb to 20 parts of water of coarsely ground herb to 500 ml of cold water; put the herb in the water and let it remain overnight at room temperature; with cold infusion it is recommended that the herb be contained in a small cotton pouch, suspended in the water overnight and squeezed out when the infusion process is complete; strain and press the marc, as also clearly taught by Green, as was a method of making herbal tinctures, which are an alcohol or aqueous alcohol solution, wherein the steps are as follows: chop and weight the plant and place it in a large jar, prepare custom menstruum, which comprises 80

proof or 100-proof vodka, wherein 80-proof vodka is approximately 40% alcohol by volume and 100-proof vodka is approximately 50% alcohol by volume; cap the jar tightly, shake the tincture frequently for 14 days, then let sit another day; decant the tincture, press the remaining wet pulp and combine the two liquids; filter if desired, that filtration is employed when the solid matter to be removed from a liquid solution is not present in a large quantity and it is done by submitting the mixture to the separating action of certain materials, which allow the fluids to pass through, but which block the passage of the solid particles, that the most common and most easily attainable filtering material used is a paper filter, such as a coffee filter, however cotton, muslin, flannel or woolen cloth may also be used, that dried plant material may be subdivided in a process called "powdering", that dried herbs are powdered prior to dispensing and that in pharmacy, the act of powdering is also referred to as comminution or tituration, which means literally to rub, crush, grind, pound and pulverize into fine particles or into a powder, that water softens and easily penetrates powdered herb, causing the powder to expand; however, alcohol has a hardening effect as it thoroughly dehydrates plant material, leaving behind only hardened cellulose and other plant solids, a menstuum containing 60 percent or more absolute alcohol tends to harden plant tissue, so a finer powder is more efficient for those plants requiring a strongly alcoholic menstruum, that powdering should be done only just prior to your actual need for it and once powdered, many of the plants constituents dissipate rapidly with the passage of time and that herbs should be stored in as whole a state as possible in order to inhibit oxidation and loss of volatile oils, and that herbal powders can be administered in capsules or orally as it is

being placed on the tongue, as clearly taught by Green, as was a method of isolating tannins from *Tripterygium wilfordii* (which is synonymous with *Tripterygium hypoglaucum*) by column chromatography using a YWG column and using methanol and buffer as the eluant, as clearly taught by Hu, as was a method of analyzing icariin in medicines containing *Epimedium brevicorum*, wherein ODS is used as an analytical column and methanol and buffer is used as an eluent, as clearly taught by Li, as was a method of extracting and isolating an active component from *Lycium barbarum* comprising passing an extract of *Lycium barbarum* through a cation-exchange column and the effluent is derivatized prior to high performance liquid chromatographic separation on a Zorbax-C8 column, wherein the mobile phase is methanol and buffer, as clearly taught by Xie, as was a method of identifying seeds of *Cusuta chinensis* by running a sample on a Hypersil-ODS column with methanol and a buffer as the eluent, as clearly taught by Ye.

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that *Tripterygium hypoglaucum*, *Epimedium brevicornum*, *Lycium barbarum* and *Cuscuta chinensis* are effective ingredients in compositions for treating rheumatism, it would

have been obvious to combine these plants with the expectation that such a combination would be effective in treating rheumatism. Thus, combining them flows logically from their having been individually taught in prior art.

Furthermore, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose an amount of active ingredients in a composition comprising *Tripterygium hypoglaucum*, *Epimedium brevicornum*, *Lycium barbarum* and *Cuscuta chinensis* for use in a method for treating rheumatism, it would have been merely a matter of judicious selection and routine optimization to choose a suitable administration form to more efficiently administer the medication, it would have been well within the purview of one of ordinary skill in the art to adjust the density of the eluting liquors and it would have also been well within the purview of one of ordinary skill in the art at the time the invention was made to modify the temperature at which an extract was prepared, which solvents to use and in which proportions, what methods of separation and purification to use, the number of times each step of an extraction is performed and to adjust the ratio of solvent to solid, thereby adjusting the relative density of a solution, because at the time the invention was made, each of the claimed ingredients was known to be useful in treating rheumatism, as were methods of preparing extracts of herbs in making medications for treatment of various aliments. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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April 3, 2007

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